1 R01 MH094448-01A1: Assessment of the Efficacy of the Female Athlete Body Project

Protocol

PBRC Institutional Review Board FWA 00006218

Approved On 7/10/13
Signature

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Introduction

The following protocol is based on a three-site study. The Pennington Biomedical Research Center (PBRC) will serve as the lead research center/coordinating center of the overall study as well as oversee one of the sites of the study, Louisiana State University (LSU). The three sites for the study include: 1.) Baton Rouge, LA: LSU, 2.) American University (AU), and 3.) San Antonio, TX: Trinity University (TU)/University of Incarnate Word (IW)). PBRC will be responsible for data collection and analysis for the three sites. Dr. Stewart serves as the contact PI for this study and Dr. Carolyn Becker (Trinity University) serves as the Co-PI for this study and Kelly MacKenzie serves as a co-Investigator for this study (American University). They will oversee operations at the San Antonio and Washington sites respectively. See Appendix A for the leadership plan for the overall study.

Objective

The goal of the present study is to test the efficacy of an intervention, called Healthy Weight (HW), designed to improve body satisfaction, promote awareness of the Female Athlete Triad, and reduce eating disorder (ED) risk factors among female collegiate athletes, when these interventions are implemented according to the needs/desires of specific social systems, such as departments of athletics. Based on previous promising findings, the departments of athletics involved in the study have chosen to implement HW to all athletics team on a mandatory basis on a staggered schedule. Given that it is unethical to require human subjects to participate in research, the proposed study (i.e., the study) must be separated from the program (i.e., the athlete prevention program) it aims to assess. Thus, the overall study will evaluate (via assessment measures) the program that the departments of athletics deliver at three sites, i.e. LSU, TU/IW, and AU.

For the local PBRC site (LSU), as well as the TU/IW, and AU sites, the departments of athletics has agreed to allow us to test the program they wish to deliver on a particular schedule (baseline, 3 weeks, 6, 12, and 18 months) compared to a brochure control group (which they will also deliver to athletes).

Program Summary

Because the proposed study (assessments only) is tied to a program that both study participants and non-study participants will receive, the program is described first.

The Program

HW for athletes will consist of participation in three one-hour and thirty minute sessions. Participants in the program will be randomized to either three sessions the HW program or a brochure waitlist control condition. The program will follow a group randomization design. The <u>study</u> will examine the effectiveness of this <u>program</u> when it is implemented without doctoral level clinicians, and while addressing the "real world" constraints of a relevant system (i.e., delivered by a competitive athletics program- LSU). The <u>program</u> will utilize the training model developed for Becker et al. to train undergraduate female athletes as peer facilitators.

Randomization. Randomization will occur by entire team. Thus, during the first year of the program 50% of the teams will be randomized to the HW program and the other 50% will be randomized to the brochure control condition. During the second year of the program, participants who were randomized to HW will be randomized to the control condition and vice versa. For the overall study, twenty- eight athletic teams (LSU=10, TU/IW= 11, AU=7) from three sites will be randomly assigned to either the HW program or a brochure waitlist control condition. For LSU specifically, 10 teams (anticipated 200 athletes) including basketball, volleyball, soccer, swimming, track, tennis, golf, softball, gymnastics, and cheerleading, will be randomly assigned to either the HW program or control condition. Statisticians at PBRC will conduct the randomization for the three sites so procedures are consistent across sites.

Peer Leader Recruitment and Training. HW will be delivered by peer leaders from the athletic teams. Athlete peer leaders will be nominated by coaches and/or head athletic trainer. The departments of athletics across the three sites will recruit approximately 2.5 leaders per team per site, resulting in a total of 76 (LSU= 30, TU/IW= 28, AU=18) peer leaders for the study. One, and ideally two, leader(s) from each sport will be recruited. At least one peer leader from each sport will lead HW within that team. For example, when the soccer runs, at least one leader from soccer will be included in the team of three leaders who will lead the group. The other peer leader(s) will come from other sports. Because groups will not all be run simultaneously, we can substitute leaders from another team if a leader becomes unavailable. Peer leaders will be trained in delivery of HW using the approach from the pilot athlete trial and the sorority trials. Leaders will complete training during their off-season and we will work to accommodate athletes' schedules. Peer-leaders will then attend two 4-hour experiential training sessions. As noted above, training sessions involve having peer-leaders lead abbreviated versions of the intervention sessions with supervision in rotation, such that each peer-leader not only leads each session and receives supervision, she also participates while other peer-leaders lead and hears their supervision. The project manager and research assistants will be responsible for scheduling peer leader training and preparing and organizing training materials, and will attend training sessions to act as participants and to provide additional supervision.

<u>Timing of Groups.</u> HW program sessions delivered by the peer leaders will take place during the off season for each team (e.g., soccer will complete the program during the spring, and swimming during the early fall).

The Study

The study examines the effectiveness of a healthy weight prevention program in female collegiate athletes. Because individuals in charge of social systems (e.g., athletics departments) typically want to implement programs to all members of the system, and have the authority to semi-mandate members into programs, the study will be separated from the program it assesses. The study will consist of participants completing baseline, post intervention (3 weeks), 6, 12, and 18 month follow-up measures to assess the utility of the interventions. This study will investigate whether or not these interventions remain effective when implemented under conditions with a higher degree of generalizability than in previous studies. It also will extend prevention research into an important eating disorders target population, namely female athletes. Finally, it further explores the use of peer facilitators and the use of existing social systems, such as athletic departments, in eating disorders prevention.

Background

Early ED prevention efforts proved largely unsuccessful (5). Evidence, however, supports the efficacy of HW in reducing ED risk factors, ED symptoms, and ED onset among females with body dissatisfaction (1, 6). Research also shows HW can be tailored for specific social systems (e.g., sororities, athletes), which can facilitate dissemination, and that undergraduate peer-leaders can implement HW successfully (7). Interventions that can be tailored to the specific needs of high risk populations (e.g., athletes) and administered affordably by endogenous providers, such as peer-leaders, are more likely to be disseminated, as indicated by the large scale dissemination of peer-led ED prevention program by a national sorority (8). Research indicates that disordered eating among female athletes is prevalent, and that this group is often at greater risk for developing EDs versus non-athlete females (2, 9). Athletes often believe that extreme thinness or very low body fat will enhance performance, and in one study, as many as 70% of NCAA Division (D)-I female athletes had insufficient caloric intake to support their daily energy needs (10). Disordered eating is especially dangerous in female athletes because it increases risk for the Female Athlete Triad (i.e., low energy availability, menstrual disorders, and decreased bone mineral density) and subsequent injury (11). Moreover, the Triad puts athletes at risk for serious long-term health consequences, such as osteoporosis, reproductive disorders, and cardiovascular disease (12). Despite this, efforts aimed at prevention of EDs among this group remain extremely limited. Because of the health risks associated with the Female Athlete Triad, interventions for

athletes need to explicitly address the Triad. To date, peer-led HW has been modified for female athletes and had its feasibility evaluated in one pilot study (4). The present study aims to extend the work of this pilot study. The long-term objective of this work is to aid in the implementation and dissemination of efficacious/effective ED prevention programs.

Specific Aims and Hypotheses

The goal of the present study is to test the efficacy of the HW program when it is implemented by the LSU, TU/IW, and AU departments of athletics. To achieve this objective, the SPECIFIC AIMS of the present study are:

Aim 1: Examine the efficacy of HW ED Prevention Program.

<u>Hypothesis:</u> HW will produce significantly greater reductions in ED symptoms, body dissatisfaction, and thinideal internalization, relative to a brochure waitlist control condition among female collegiate athletes at posttreatment and at 6-month, 12-month, and 18-month follow-ups.

Aim 2: Examine the impact of HW ED Prevention Program on secondary outcomes.

<u>Hypothesis:</u> HW will result in significantly greater increases in knowledge and identification of the Female Athlete Triad, and greater treatment seeking for the Triad, as well as decreases in negative affect and associated health care utilization compared to the brochure waitlist control condition.

Aim 3: Investigate mediators (underlying mechanisms) hypothesized to account for the intervention effects of the HW ED prevention program.

<u>Hypothesis</u>: Shape and weight concern (body dissatisfaction) will mediate the intervention effects of the HW ED prevention program. Note: We also will explore other potential mediators such as knowledge of the Female Athlete Triad and both traditional and sport thin-ideal internalization given that the mediator literature available for HW is quite limited and many possible factors have not been tested.

Methods

Based on past experience and stated preferences from athletics departments, we know that departments and/or coaches might choose to provide the program to all of their athletes. Thus, we have separated the program which consists of randomized delivery of HW or brochure control from the actual research study, which consists of only the assessments.

To achieve the above aims, as part of the <u>program</u>, 28 athletic teams will be randomly assigned by entire team (group/cluster randomization) to either peer-led HW (delivered by LSU, TU/IW, AU athletics departments) or a waitlist brochure control, which will receive the HW program after 18 months. For the <u>study</u>, baseline plus follow-up assessments will be conducted at 3 weeks (posttest), 6 months, 12 months, and 18 months. <u>Thus, student athletes may participate in the HW intervention, but choose to abstain from the associated research study (assessment measures). Given that it is unethical to require human subjects to participate in research, the proposed study (i.e., the study) must be separated from the program (i.e., the athlete prevention program) it aims to assess. This design is consistent with other studies that have implemented peer-led HW in collaboration with defined social systems such as sororities and athletics, and reflects a model that is viable for dissemination and implementation research with evidence-based prevention interventions.</u>

Participants

It is anticipated that 500 athletes across the 3 sites will participate in the overall study. Specifically, the LSU site anticipates enrolling 200 athletes who meet the following inclusion criteria:

- a) female
- b) member of a University-sponsored athletic team
- c) are willing and able to provide informed consent, attend all study visits, and comply with the study protocol
- d) can read

There are no exclusion criteria in order to maximize generalizability and dissemination.

Recruitment.

Participants will be recruited through their athletic teams. Individual coaches or athletic directors may choose to provide the HW program department-wide to their female athletic teams. If the coach or director chooses to encourage participation in the program in any way, actual study participation, which consists only of the assessments, will always be voluntary. All available ethnic groups will be actively recruited in order to maximize generalizability of the findings.

Study Participation.

As aforementioned, female athletes participating in the program will be given the opportunity to voluntarily participate in a study evaluating the efficacy of the HW program. Research staff will meet with the athletes at a time determined by the athletic trainers and/or coaches. During this meeting, research staff will describe the nature of the program and the nature of the study, emphasizing that although the program may be provided by individual athletic teams or departments, participation in the surveys and interviews that comprise the study will be entirely voluntary. In cases where the HW program is provided, we will repeatedly remind participants that the study is voluntary and that coaches will not be informed regarding who did and did not participate in order to reduce the likelihood that participants feel coerced into participating in the study. It will be explained that there is no penalty for choosing not to participate. For the self-report written assessments, we will ask participants to sit in a large circle with their backs to each other so as to reduce the likelihood that fellow teammates will see whether or not a given athlete is filling out the forms. We will hand out packets containing consent forms, contact forms, and all questionnaires. Participants will be told the forms will be separated to maintain anonymity. After the participants have consented to the study and completed informed consent, they will complete all forms. All athletes will be instructed to sit remain seated until asked to leave so that no one is aware of who has chosen to participate or not. After ample time has been given for participants to complete forms if desired, athletes will be asked to exit the room and turn in forms regardless of if they were completed or not. Consents will be placed in one file where staff will make sure it was completed completely. In another pile, questionnaires will be turned in. Staff will check questionnaires for completeness. If a question is left blank, the participant will be asked to initial and date to indicate this was done on purpose. Minors (under the age of 18) will be given an assent form that must be signed prior to study initiation. Further, we will conduct phone interviews with interviewers blinded to the participant's identity (another individual will call the person for the interview, then hand over the phone to the interviewer) so students will not be able to be identified. It is of critical importance to the participating athletic departments that participation in the research study (completion of assessments) be conducted in a way that ensures the anonymity of the athletes. Thus, we will employ methods to collect data from self- report measures and phone interviews to achieve this aim. With regard to identifying individuals in the study with EDs, it is important to note that the proposed athletic departments feel confident that they are able to identify cases of EDs with their existing contingency plans. We also will provide referral information to all participants in order to seek help for ED related problems (see Human Subjects section). Any participants who are identified as having an ED by the athletic department will be permitted to remain in the program unless the athletics department medical staff, (trainers/physicians/psychologists) decide that it is not beneficial to have an athlete participate.

Procedures

Study assessments will occur at baseline, post-test (3 weeks), 6-, 12-, and 18-month follow-ups. Participants will complete the assessments on site on the appropriate time point. For baseline assessments, minors (participants aged 17 and under) will be given minor consent and assent to sign and get signed by parents/guardians prior to participating in their baseline assessment. If possible, this will be done in a special meeting prior to the baseline assessment meeting so that minors may participate with their team members at

the measurement sessions. Also, the minor may turn 18 sometime during the study and at that time, the participant will be re-consented as an adult for the study. At each assessment, participants will complete self-report questionnaire measures that assess the outcomes, as well as a brief individual telephone interview assessing ED symptoms (see Table 1 for the assessment schedule). The interviews will be administered by an independent assessor based out of the Baton Rouge, LA site (PBRC), who will be kept blinded to the participants' intervention condition.

Compensation

There is new legislation, NCAA Bylaw 16.11.1.10.2 (57), which allows Institution-based research studies to compensate student-athletes for participation in a research study involving only student athletes. Thus, participants will be compensated for completing each of the 6 assessment time points in the form of Amazon gift cards. Participants will be given \$20 for the written self-report assessments and \$30 for the interview assessment (\$50 total for each assessment time point in gift cards) at baseline, post-intervention (3 week), 6-, 12-, and 18-month follow-ups (for HW), respectively.

Assessment Protocol and Schedule

Table 1. Assessment Schedule

	Baseline	Intervention		Follow-up)
Measure	Wk 0	Wk 3	6 mo	12 mo	18 mo
Informed consent	Х				
Demographics	ιX		,	***************************************	
Main Outcomes					
Eating disorder symptoms (EDE interview)	Х	X	Х	Х	Х
Eating disorder symptoms (EDE-Q)	Х	Х	Х	Х	Х
Thin-ideal internalization (IBSS-R)	Х	Х	Х	Х	Х
Thin-ideal internalization (questionnaire)- athlete version	Х	х	Х	Х	Х
Secondary Outcomes			, , , , , , , , , , , , , , , , , , , ,		
Health care utilization (HSUS)	X	X	Х	Х	Х
Teammate Relationship Health (TRHS)	Х	Х	Х	Х	Х
Knowledge of Triad	Х	Х	Х	Х	Х
Negative affect (PANAS-X)	Х	X	Х	Х	Х
Intervention Expectancy/Credibility	and Adhe	erence			
Intervention suitability/expectations	Х	Х			
Study Information Questionnaire"	Х	Х	Х	Х	Χ
Self-perception of Performance measure	Х	Х	Х	Х	Х
Athlete Body Project Eating Questionnaire	Х	Х	Х	Х	Х
Program Satisfaction Questionnaire	Х	X	Х	Х	Х
Contextual Body Image Questionnaire – Athletes				Х	Х
Currently In Sport				Х	Х
Training Attitudes Scale				Х	С

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Assessment Measures

See Appendix B for the assessment measures.

<u>Demographic data</u> will be collected via self-report (e.g., age, gender, race/ethnicity, parental education, height, weight), as well as information regarding athletic division and degree of perceived competitiveness within the division.

Primary and Secondary outcomes

Eating Disorder Examination (EDE; (58)). A brief adapted form of this semi-structured interview assesses DSM-IV ED symptoms over the past three months. Items assessing the symptoms in the past month are summed to create an overall ED symptom composite for each assessment, as done previously (6, 59). The symptom composite has shown internal consistency (α = .92), 1-week test-retest reliability (r = .90), sensitivity to detecting intervention effects, and predictive validity for future onset of depression in past studies (59, 60). Participants can also be given a diagnosis of threshold or subthreshold anorexia nervosa, bulimia nervosa, and binge ED. This adapted version of the EDE has demonstrated high test-retest reliability for threshold and subthreshold diagnoses of anorexia nervosa, bulimia nervosa, and binge ED (r = .96), and high inter-rater agreement (r = .86; (1)). In the proposed study, the EDE will be utilized for Aim 1 and Aim 3 (ED composite score).

Eating Disorder Examination Questionnaire (EDE-Q; (61)). The EDE-Q is a self-report version of the EDE, which is commonly viewed as the gold standard in the assessment of EDs. The EDE-Q assesses eating attitudes and behaviors over a 28-day period. It has four subscales: restraint, weight concern, eating concern, and shape concern. This scale has shown internal consistency and reliability (62). The EDE-Q will be utilized for Aim 1 and Aim 3 (ED composite score; body dissatisfaction via the weight and shape concern subscales). Ideal-Body Stereotype Scale-Revised (IBSS-R; (63)). We will assess internalization of the traditional thin-ideal with the IBSSR (sample item: "Slender women are more attractive"). Participants respond using a 5-point response format ranging from "strongly disagree" to "strongly agree." Items are averaged for analyses. This scale has shown internal consistency (α = .91), 2-week test-retest reliability (r = .80), and predictive validity for bulimic symptom onset (6), as well as sensitivity to detecting intervention effects (1). Athletes often experience pressure to obtain a sport-specific body type. Thus, we will also modify the IBSSR measure to be suitable for the athlete population (see below). This measure will be utilized for Aim 1 and Aim 3 (thin-ideal internalization). Thin-ideal internalization (questionnaire)- athlete version. We will assess internalization of the athlete thin-ideal with the IBSSR- athlete version This measure will be utilized for Aim 1 and Aim 3 (thin-ideal internalization).

Positive and Negative Affect Scale-Revised (PANAS-X; (64)). Negative affect will be assessed with the sadness, guilt, and fear/anxiety subscales from the PANAS-X. Participants report the extent to which they felt negative emotional states on 5-point scales ranging from "very slightly or not at all" to "extremely". This scale has good internal consistency (α = .95), 2-week test-retest reliability (r = .78), predictive validity for bulimic symptom onset, and sensitivity to intervention effects (6, 63, 64). This measure will be utilized in Aim 2 (negative affect).

<u>Health Survey Utilization Scale</u> (HSUS; (65)). Health care utilization will be assessed with the HSUS, which assess frequency of utilization of health and mental health services (sample item: In the past six months, did you get health care for a medical problem or an illness when you were feeling sick?). If participants endorse health care service utilization, they are asked to indicate the primary reason for treatment. The scale has demonstrated acceptable reliability (r = .77) and 20-week test-retest reliability (r = .62; (66)). This measure will be utilized in Aim 2 (health care utilization).

Teammate Relationship Health Scale (TRHS). Modified from the community index of the Relational Health (RH) Indices (67) by changing "this community" to "my sports team." The 14- item community RH Index has been shown to have good internal consistency (α = .90; (67)). Correlations in the predicted directions with related measures support the concurrent and convergent validity (67). This measure will be utilized in Aim 2. Knowledge of the Female Athlete Triad. Knowledge of the Triad will be assessed with 10 true/false or multiple-choice items. The percent of correct answers will be used to determine whether knowledge increased significantly as a function of condition. This measure will be utilized in Aim 2 and Aim 3.

<u>Study Information Questionnaire.</u> This self-report questionnaire assesses cross contamination between the Female Athlete Body Project program and control group by asking specific questions about material included in the active intervention.

<u>Self- Perception of Performance Measure.</u> This self- report questionnaire assesses the athlete's self-perception of performance over the last 5 episodes of competition.

Athlete Body Project Eating Questionnaire - This general eating questionnaire assesses key eating behaviors emphasized in the Female Athlete Body Project program.

<u>Program Satisfaction Questionnaire</u>-This questionnaire assesses participants' general satisfaction with the Female Athlete Body Project program.

Contextual Body Image Questionnaire-Athlete-This questionnaire assesses participants' body image perceptions within the context of daily life as well as within their sports environment.

Currently In Sport-This questionnaire assesses whether the athlete is still currently participating in their college sport.

<u>Training Attitudes Scale</u>-This questionnaire assesses the athletes' attitudes, behaviors, and feelings in regards to training for their sport.

Exploratory Outcomes

Female Athlete Triad Identification. We will measure the number of athletes who self-identify with the Female Athlete Triad by asking trainers how many athletes have come forward with concerns about the female athlete triad. Prior to the start of the study, we will get baseline assessment for the past year via the athletic trainers. Self-reported Weight. Participants will self-report height and weight on the demographic forms. Although we recognize the gold standard is collection of objective height/weight, we opted for self-report in order to not draw attention to weight with the athletes and to satisfy coaches/trainers' concerns about weighing athletes. While we recognize the limitations of self-reported weight, this aim will be utilized to do exploratory analyses to gain information on whether athletes, lose, maintain or gain weight over the course of the study time points. Intervention Expectancy/Credibility and Adherence

Perceived Credibility and Expectancy. The Credibility/Expectancy Questionnaire (CEQ; (68)) will be used to assess perceived intervention credibility and expectancy for improvement. The CEQ is a commonly used 6-item questionnaire with two subscales: (a) credibility (e.g., "At this point, how logical does the intervention offered to you seem?") and (b) outcome expectancy (e.g., "How much improvement do you really feel will occur?"). Items are rated on a 0 (not at all) to 10 (extremely) Likert-type scale. The CEQ has good internal consistency (αs range .84 to .85) and test-retest reliability (rs ranging from .75 to .82; (68)).

Training and Quality Assurance

Assessment Training and Quality Assurance. Independent assessors will have a bachelors degree or higher and prior to the beginning of the study and will have completed extensive interview training on general interview skills and on the administration of the diagnostic interview (EDE) to be used in this project. Training will be led by Dr. Stewart and Dr. Becker who are highly experienced with the EDE, and will include didactics, role-plays, and tape ratings. Assessors will be required to show a minimum diagnostic agreement with supervisors ($\kappa > .85$) before starting data collection and will be required to maintain this level of agreement throughout the study (as assessed by randomly selected audiotaped interviews). Assessors will meet weekly via phone conference with Dr. Stewart for ongoing supervision and diagnostic questions requiring consensus.

Intervention Implementation Fidelity Check. A detailed intervention manual for HW has been developed to promote adherence. All sessions will be audiotaped using digital voice recorders and a randomly selected 50% of the sessions will be reviewed and rated for adherence to the intervention protocol by two independent trained raters. Raters will be required to rate a series of training tapes to establish inter-rater reliability (k > .85) before they rate the sessions. Protocol adherence will be measured using session-specific checklists for the concepts, skills, and exercises that are outlined for each session. Each item is rated for full presentation, partial presentation, or missing/minimal presentation. Past studies have found that this scale shows inter-rater agreement (ICC = .72) (69). Raters will also provide e-mail feedback to peer-leaders to promote adherence.

Procedures to minimize attrition. To minimize attrition, particularly in students who have graduated, participants will receive a reminder email or text prior to each scheduled group and assessment session and phone assessment. Second, participants will be asked for the names, addresses, phone numbers, and e-mail addresses of three individuals who "will always know where you are" so that we can locate individuals who move or change phone numbers. This information will be updated every 6 months. Third, we will send out holiday cards to participants with forwarding address requests so that we know when they move. This approach has been used successfully in previous trials in which a 95% retention rate was achieved through 3year follow-up (1). Fourth, we will utilize secure, encrypted internet-based questionnaires as an alternative option to standard paper/pencil methods in order to make follow-up more convenient and efficient - particularly for graduated students (PBRC programmer from the Psychological Assessment Lab (PAL) will oversee). Finally, since experience indicates that retaining participants at follow-up becomes more difficult because completion of assessments is no longer as convenient, as aforementioned, we will pay participants for completing each assessment. It should be noted, however, that retention at 1-year was 75% in the pilot study with athletes, despite the fact that participants were not paid and the proposed tracking procedures were not in place. Thus, we anticipate being able to increase our retention rate by utilizing these strategies and by compensating participants for assessments.

Protection of Human Subjects and Risk Benefit Analysis

Protection of Human Subjects

Human Subject Involvement and Characteristics. We estimate that there will be 500 participants in the overall study, with 200 coming from the LSU site. Inclusion-criteria include female collegiate athletes. Only female athletes will be included because a) women are greater risk for eating disorders compared to men, and b) the departments of athletics at the respective sites want to first implement this program with female athletes. Individuals that are experiencing no medical complications that would prevent them from being in the study are eligible. There are no minimum and maximum age or BMI requirements, provided that the individual is a collegiate athlete and healthy enough to participate. Participants are required to provide written consent for participation in the research project. Participants under age 18 will need to provide written assent. If participants do not provide written consent, or have a medical condition in which they cannot participate healthily in the study, they will be excluded. We should note that it seems unlikely that a participant will be healthy enough to participate in collegiate athletics but not fill out surveys and participate in phone interviews – so health is unlikely to rule out a significant number of participants.

Sources of Material. All of the data collected from participants will be solely used for the purposes of research. The data include self-report questionnaires and brief phone interviews. Questionnaire data will be collected at the participating study sites and mailed to the Pennington Biomedical Research Center (PBRC) for data entry and storage. All phone interviews will be conducted by trained research staff at PBRC. Results will only be reported for groups of participants, and no individual data will be provided to individuals not associated with the research. Collected data will be stored in a locked room for at least 5 years and eventually destroyed as per APA guidelines. There are minimal risks for participation in the study and the protocol is written to ensure the least degree of risk. All data will be collected so that the identity of each participant will be anonymous, and only the principal investigator, study coordinator, and data managers at PBRC (where the phone interviews are being conducted) will be able to link any datum to an individual. Publications and presentations of the findings will convey the results in a manner that does not disclose the identity of any individual.

<u>Potential Risks.</u> There are no known potential risks- physical, psychological, social, legal or other-in this study. None of the previously published trials have reported adverse effects, and none of the preliminary studies conducted by the Co-PI (Dr. Becker) generated any report of any adverse effect despite encouraging participants to report adverse events. Nonetheless, it is still possible that a participant might experience an adverse effect. Because the departments of athletics may want to encourage participation in the program, the program and the study are separated in the present proposal. The primary potential risk of the <u>study</u> comes from the completion of the questionnaires, which could induce distress secondary to their sensitive content.

These measures are widely used in eating disorders research, however, and we could identify no reports of adverse effects. The questionnaire data obtained from participants will be <u>kept anonymous</u> by having participants code their own questionnaires by answering a series of questions as noted below. Confidentiality and anonymity will be assured by using letter and number codes for participant data, as opposed to using names, and these codes will be created and only known by the participant. None of the research staff will have access to the knowledge needed to break these codes. Follow-up data will be collected in a similar manner.

Adequacy of Protection Against Risks

Recruitment and Informed consent. Participants are volunteers that will be recruited through athletic departments at the three sites of the study (i.e. LSU, AU, TU/UIW). The Pennington Center's Institutional Review Board (IRB) will approve the study protocol and assent and consent forms prior to initiation of the study, as will the IRBs of all institutions from which participants will be recruited. Informed consent (over the age of 18) or assent from all participants (under the age of 18) as well as consent from their parent(s) and/or legal guardian(s) (under the age of 18) will be obtained. All questions and concerns are clarified before participants sign the consent form. Prior to participating in the HW program, program participants will be informed that they have the opportunity to participate in a voluntary study designed to evaluate the program in which they are participating. Because the athletes will be encouraged to participate in the HW program, we will repeatedly remind participants that the *study* is voluntary and that coaches will *not* be informed regarding who did and did not participate, so as to reduce the likelihood that participants feel coerced into participating in the study. In addition we will take the precautions described below to limit the likelihood that individuals collecting the data (or anyone connected with the study) will know who did or did not participate in the study, and that we will not be able to link any data to specific participants.

Study participation. Athletic Trainers (or coaches) will set up an initial appointment with each team and the designated research staff person at each site. Neither the Co-Pls, coaches nor the athletic trainers will be present when participants are recruited for the study, which minimizes chances for coercion. During this meeting, the trained research staff person collecting the data will describe both the nature of the study. including incentives. We will emphasize that participation in the study is voluntary, thus, their coaches will not know who did and did not participate in the study. We also will explain that there is no penalty for choosing to not participate. Next participants will be asked if they have any questions. At this point the research staff will ask participants to sit in a large circle with their backs facing one another - so as to reduce the likelihood that fellow teammates will see whether or not a given participant is filling out the forms. They will then pass out packets containing 2 copies of the consent forms (one to sign and return and one to keep), contact forms, and all questionnaires. Participants will be told the forms will be separated to maintain anonymity. After the participants have consented to the study and completed informed consent, they will complete all forms. All athletes will be instructed to sit remain seated until asked to leave so that no one is aware of who has chosen to participate or not. After ample time has been given for participants to complete forms if desired, athletes will be asked to exit the room and turn in forms regardless of if they were completed or not. Consents will be placed in one file where staff will make sure it was completed completely. In another pile, questionnaires will be turned in. Staff will check questionnaires for completeness. If a question is left blank, the participant will be asked to initial and date to indicate this was done on purpose. Participants who don't wish to participate will be told just to hand back blank form and to keep the other blank form which they can discard at a later time. They can also place the blank questionnaires in with the stack of completed ones. When the administrator notes that the entire pack is blank, they will assume the athlete has chosen not to participate. This will reduce the degree to which it is evident to others in the room that a participant has chosen to not participate in the study.

During the interview – the participant will also be asked to create a unique identifying number (e.g., day of birth, last four of social, a number associated with the team sport and a letter associated with the school). These questions will be used to create a unique identification number that will be used to track participant data while keeping responses anonymous. These same questions will be used on the questionnaires to create the same identification numbers. The departments of athletics with which we are working feel it is critical to place anonymity above the potential for ED identification for the following reason a) to reduce coercion, b) to reduce fear on the parts of the athletes that their data will not be confidential and c) because they already have

extensive knowledge of athletes eating behaviors and risk for EDs. In sum, the athletic departments do not want the study to help identify ED cases because they feel capable of doing that with their current policies and want data to be as anonymous as possible. Completed contact forms will be folded before being put in a large envelope.

While the students fill out the contact forms, the research staff will follow procedures to track consent separately from questionnaires to maintain anonymity. All tracking systems will be maintained separately to maintain anonymity and preserve data integrity. This will be used for tracking participation for the incentive payments.

Next, we will hand out the questionnaires. Participants again will be told that if they choose to not participate, they can hold onto the copy of the questionnaire and either sit quietly or pretend to fill out the questionnaire while actually leaving it blank so as not to indicate to teammates who is and is not participating. All program participants will then give their questionnaire to the research staff so it can be placed in a large envelope. The research staff person will be waiting just outside the door and will allow one student at a time to turn in the questionnaires. If the student turns in a completed questionnaire packet, she will asked her name and the appropriate box on the index card will be checked off.

Consent forms will be stored in a separate filing cabinet from the one where we will store data. No one other than the Co-PIs or appropriate research staff will have access to any information provided on the consent form. As part of the introduction to the program and study, we will provide all program participants with the phone number to the appropriate College Counseling Centers and/or nearby clinics and encourage them to either seek care there or seek an outside referral, if they either experience any negative effects or if the program causes them to realize that they have eating related problems. Because the departments of athletics have repeatedly emphasized to us that they place a premium on anonymity - we have no plans to link specific participants with their data. Indeed, with the exception of the phone interviews, we will be completely unable to link data to specific individuals, and even in this case - we intend to keep the interviews as anonymous as possible. Thus, we cannot (in the vast majority of cases) and will not use the data to identify participants with eating disorder concerns. The athletic departments with which we are working have repeatedly assured us that they have in place the capability to identify and take care of eating disorders cases in their departments (note: in large part this is because the athletes and coaches (and at times the trainers) eat together on campus and on the road when traveling to games. Thus eating behavior, bathroom behavior, weight and exercise behavior are easily observed by the departments. Moreover, student athletes report problematic behavior on the part of fellow teammates to coaches and/or trainers). Thus, no part of the present study has been designed with the intention of identifying cases.

Protection against risks. Efforts to minimize the potential risks of the assessment methods and outcome variables include frequent monitoring by the investigators to assure that no volunteer suffers any adverse effects from participating in the research. All volunteers are assured of their confidentiality both verbally and in the informed consent forms. The research facilities are strictly limited to the staff of the research institution and to research volunteers. This is accomplished by a variety of stringent security measures. All data records are stored in locked areas. Access to these areas is limited to the research support staff, director of the clinical facilities, and the PIs. Participants' research records are filed according to ID numbers. All forms on the chart, with the exception of consent form, display only the ID number. Electronic data storage is similarly restricted with only the PIs and authorized persons having access to databases containing confidential clinical records, i.e. those containing identifying information. This study will follow all of the guidelines for the use of human subjects that have been outlined by the Institutional Review Boards at the participating universities. Although the current project has yet to be reviewed by the relevant IRBs, it is modeled after both the sorority prevention trials and the athlete pilot study, all of which were approved by the IRB after full review. Per NIH policy and ethical guidelines with respect to human subjects research, the project will only proceed once approval is granted by the relevant IRBs.

Potential Benefits of the Proposed Research to the Subjects and Others

Past research indicates that the HW intervention to be used in this study significantly reduce a range of eating disorder risk factors. Thus, there is a good chance that participants will directly benefit from participation in the

participants there are few additional benefits offered by participating in the study. The overall societal benefit of determining whether or not such interventions are an effective option for athletic departments is substantial, however. Thus, given that the risks of participation in the study are relatively low, it appears that the benefits to society and female athletes as a whole easily outweigh the risks.

Risk/Benefit Ratio

The low risks of the study appear to be balanced by the anticipated benefits to the scientific and medical communities and ultimately, to society as a whole.

Importance of Knowledge to Be Gained

The proposed investigation will produce informative information pertaining to the impact of an intervention (*Healthy Weight; HW*) on eating disorder risk factors and the female triad in female collegiate athletes. These new data will have implications for prevention of eating disorders. The results could ultimately lead to the development and dissemination of eating disorder and female triad prevention programs for women.

Data Management

PBRC in Baton Rouge will serve as the primary site of the study. Assessment data in the form of scannable self-report questionnaires will be mailed to PBRC from the other study sites. For follow-up assessments, for athletes who may have graduated or are no longer at the universities, we will utilize secure, encrypted internet-based questionnaires as an alternative option to standard paper/pencil methods in order to make follow-up more convenient and efficient – (PBRC programmer from the Psychological Assessment Lab (PAL) will oversee).

Data and Safety Monitoring Plan

This study will utilize a data and safety monitoring board (DSMB). The DSMB will meet quarterly via conference call. Prior to the start of recruitment, the DSMB will give formal approval of the study protocol and informed consent.

- a. <u>Size and Composition.</u> The DSMB will consist of 5-6 members both internal and external to the Pennington Biomedical Research Center. The planned composition is as follows: Biostatistician (1), Clinical Psychologist (1-2), Ethicist (1), and Layperson (1-2). A member of the DSMB will serve as the Safety Officer and lead the DSMB.
- b. Major Responsibilities of Members
 - 1- Sign and abide by a statement of confidentiality
 - 2- Disclose any actual or potential conflicts of interest
 - 3- Be familiar with research protocol and plans for safety monitoring
 - 4- Oversee safety of participants to include review of adverse events
 - 5- Review reports of related studies, as appropriate
 - 6- Review major proposed modifications
- c. Reports. Following each meeting, the DSMB will provide written documentation regarding findings for the study as a whole and any relevant recommendations related to continuing, changing, or terminating the study. All DSMB recommendations will be submitted to the Principal Investigator and/or his designee, with a copy provided to the Pennington Biomedical Research Center IRB and NIH Project Officer or designee. This report will also be submitted to the Associate Executive Director of Clinical Research at Pennington to be presented and discussed at the monthly Medical Staff Meetings.
- d. <u>Qualifications and Responsibilities of the Safety Officer.</u> The Safety Officer for this trial will be familiar with the adverse event definitions and reporting requirements for the study. The Safety Officer will

- review reports sent by the study coordinator as they occur and will determine whether there is any corrective action or stopping rule violation. The safety officer will send written documentation of the decision to the PI and NIH, and the Associate Executive Director of Clinical Research.
- e. Reporting of Adverse Events. Adverse events will be reported to the study PI, Project Manager, statistician, Chair of IRB(s), Chair of the study DSMB, and Safety Officer throughout the trial. Adverse event data will be analyzed quarterly, but serious or life-threatening adverse events require immediate reporting and follow-up. We anticipate most adverse events will be mild and the participant will be able to resume intervention activities or will be referred out of the study for help (e.g. eating disorder symptoms). For example, in our previous research, we observed no differences in serious adverse events or all adverse events between the Healthy Weight intervention group and the brochure control group.
 - If the study participant experiences psychological or emotional distress, the project staff will
 cease research activities and attempt to calm and reassure the participant. The participant will be
 directed to an appropriate health care practitioner or other mental health referral for further
 assessment and treatment as needed.
 - The investigator and/or project staff present at an adverse event will record detailed narrative
 notes describing the adverse event. The principal investigator will complete the form <u>Notification of an Adverse Event</u>.
 - All adverse events will be reported to the IRB of the Pennington Biomedical Research Center and
 to the IRB of the collaborating institution if that event occurred in San Antonio, TX or Washington,
 DC. Serious adverse events will be reported within 48 hours. Other adverse events that are not
 serious but are unexpected and are associated with the study procedures will be reported within 10
 days.
- f. Stopping Rules. There is minimal risk for participating in this trial, particularly since the study only consists of completing the assessments (i.e., female athletes will have the option to participate in the intervention but choose to not participate in the study, which consists of completing the assessments). The most likely scenario that would indicate a cessation of the study would be failure to recruit participants or implement the intervention as planned. Nevertheless, in addition to monitoring recruitment and completion of the assessments, we also will monitor the rates of development of psychological symptoms. The safety officers, in conjunction with the study investigators, will alert the IRB, NIH, and DSMB if a larger than reasonably expected psychological symptom development rate occurs in the treatment or control groups. Other issues that are related to the stopping rules include:
 - New information It is unlikely that new information will become available during this study that would result in discontinuing the trial.
 - Limits of assumption It is possible that the value of data analysis will be limited by differences between the intervention groups at baseline or because of study dropouts or missing data. Baseline differences will be analyzed annually and effects on the power to detect differences in the outcome measures will be evaluated and discussed with the PI, safety officer, and the NIH Project Officer. Although an excessive number of dropouts could occur, this has not been our past experience. In the pilot study, the dropout rate was only 23% at one year with no participant incentives. The present study will, however, include incentives for participation. Thus, if the dropout rate for the proposed study exceeds 15%, the safety officer will initiate a meeting with the PI to discuss strategies to increase retention. If the dropout rate exceeds 25%, the safety officer will meet with the study investigators to determine whether or not the study should continue.
 - <u>Limit of rules</u> We acknowledge that circumstances, other than what are listed, may justify stopping the study.

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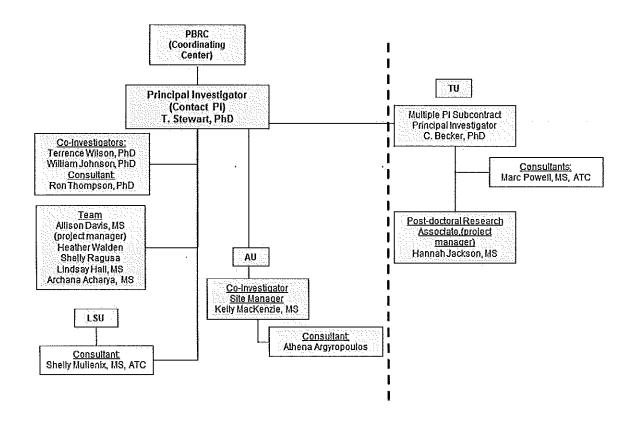
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APPENDIX A

LEADERSHIP PLAN

The organizational chart below outlines all of the personnel and their relationships in the study organization.



Pennington Biomedical Research Center (PBRC) will serve as the coordinating center for the study and will oversee the Louisiana State University (LSU) and American University (AU) sites. Dr. Stewart (PBRC) will serve as the contact PI for the study and will be responsible for collaborating with Dr. Becker (Trinity University, TU), Ms. Mackenzie(AU), Terrence Wilson (Rutgers), and William Johnson (PBRC) as well as the Executive Steering Committee on all aspects of the total project, ensuring that research goals are met in a timely manner, that the work is done within budgeted amounts and is in compliance with Universities and funding agency regulations, that recruitment progresses on schedule, and that data are collected properly and written up for publication.

Dr. Stewart will participate in monthly conference calls with Dr. Becker and Ms. Mackenzie as well as quarterly calls with the steering committee. Dr. Stewart will host a training summit at PBRC for all of the sites

participating in the study (will be attended by Dr. Becker and Ms. MacKenzie. and project managers at both sites) to kick off the study. Dr. Stewart will also engage in one video conference call per quarter with the steering committee. For both Louisiana State University (LSU) and American University (AU), Drs. Stewart and Becker will share responsibility for providing training, supervision and feedback for peer facilitators, data processing, and data analyses and interpretation of the results. Dr. Stewart will collaborate with Dr. Becker on manuscript preparation and presentation of findings at national conferences.

EXECUTIVE STEERING COMMITTEE

The study has identified an **Executive Steering Committee** whose function is to oversee the overarching success of the study. The Executive committee is composed of the following members outlined in the chart below:

Personnel	Title	Expertise/Role
Tiffany Stewart, Ph.D.	PI, Contact PI PBRC/LSU	Eating disorders and body image prevention and treatment. Experience in design, implementation, and dissemination of multi-site randomized controlled trials with group (cluster) randomization design and methods. Overall oversight of the project. Oversight of the LSU and AU sites. Overall responsibility for data accrual, analysis and dissemination of findings.
Carolyn Becker, Ph.D.	PI (Multiple PI Subcontract) TU	Eating disorders and body image prevention and treatment. Experience in participatory research, randomized controlled prevention trials, and in developing and conducting peer-led prevention programs for eating disorders. PI of pilot study of HW program in athletes. Oversight of TU site.
Ron Thompson, Ph.D.	Consultant	Assessment and treatment of eating disorders in athletes. Regular collaborator with the NCAA and International Olympic Committee Medical Commission. Consultant on the athlete population.
Terrence Wilson, Ph.D.	Co-Investigator	Established researcher in the field of eating disorders and body image, with extensive experience in design, execution, and dissemination of multi-site randomized controlled trials. Consultant on eating disorders and body image and multi-site study implementation.

Executive Steering Committee Meetings: The Executive committee is expected to provide oversight and guidance of the policies and procedures of the study and will meet via conference call one time per quarter and via videoconference call once per year. Minutes shall be kept and disseminated to all Investigators and Consultants, so that all are kept abreast of the study progress. Additional calls and email communication by Steering Committee members and staff members will be utilized as needed to tend to the daily happenings of the study at all sites.

The agenda for the Steering Committee meetings during the study is outlined below:

- a. Principal Investigator's report- update on overall aspects of study, issues, and progress: Stewart.
- b. Status of recruitment of peer leaders: PBRC (Stewart); TU (Becker) AU (Stewart)

- c. Report on Peer lead groups: PBRC (Stewart); TU (Becker); AU (Stewart)
- d. Update on data collection and database: Stewart
- e. Old Business
- f. New Business

Conflict Resolution: In the event of conflict in the course of the study, all attempts shall be made to resolve the conflicts based upon our institutions' mutual commitment to civility and fair play. The PI, Dr. Stewart, will make all attempts to resolve the conflict and will call upon the senior scientists who serve as consultants to advise her in this regard. It is unlikely that these senior executives will be unable to find a fair resolution of any conflicts that arise. In the unlikely event that the issues involve disputes between the study sites that are unresolved even with the intervention of the consultants, then, the conflict shall be referred to senior executives at each study site so that arbitration of the conflict can occur. No members of this arbitration panel shall be directly involved in the research on in consulting with the study.

Data Management: PBRC in Baton Rouge will serve as the primary site of the study. Assessment data in the form of scannable self-report questionnaires will be mailed to PBRC from the other study sites. PBRC has extensive experience with receiving and banking data, merging the data with the central database and data analysis without any problems.

Fiscal and Management Coordination: Fiscal and management coordination at PBRC will be overseen by Mark Alise, Ph.D., Associate Executive Director of Administration and Finance: Fiscal and management coordination at TU will be overseen by Mary Jump, Grants Officer. Fiscal and management coordination at AU will be overseen by Frank Wilson, Comptroller.

Scientific Publications: Publication authorship will include representation from all participating institutions and will be based on the relative scientific contributions of the PIs and key personnel.

APPENDIX B

Assessment Measures

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DEMOGRAPHICS

Date of Birth: Age:				
<u>Ethnicity</u> Hispanic or Latino Not Hispanic or Latino				
<u>Race</u> American Indian or Alas Asian Black or African America Native Hawaiian or Othe White	an			
Height				
Weight				
What is the highest leve	l of education obtained by	your		
Mother (please circle)				
Less than high school Masters Doctorate	High School Graduate	Some college	Bachelors	Some graduate school
Father (please circle)				
Less than high school Masters Doctorate	High School Graduate	Some college	Bachelors	Some graduate school
What NCAA Division lev	vel is your team?			
Division I Division II Division III				

Within your Division – how competitive do you believe your team is? Highly Competitive Competitive Somewhat Competitive Not Very Competitive

How many days out of the past 28 days	No	1 to 5	6 to 12	13 to 15	16 to 22	23 to 27	Every	
How many days out of the past 20 days	days	days	days	days	days	days	day	
Have you been deliberately trying to limit the amount of food you eat to influence your shape or weight?	0	1	2	3	4	5	6	
Have you gone for long periods of time (8 hours or more) without eating anything in order to influence your shape or weight?	0	1	2	3	4	5	6	
Have you tried to avoid eating any foods which you like in order to influence your shape or weight?	0	1	2	3	4	5	6	
. Have you tried to follow definite rules regarding your eating in order to influence your shape or weight; for example, a calorie limit, a set amount of food, or rules about what or when you should eat?	0	1	2	3	4	5	6	
Have you wanted your stomach to be empty?	0	1	2	3	4	5	6	
Has thinking about food or its calorie content made it much more difficult to concentrate on things you are interested in; for example, read, watch TV, or follow a conservation?	0	1	2	3	4	5	6	
Have you been afraid of losing control over eating?	0	1	2	3	4	5	6	
Have you had episodes of binge eating?	0	1	. 2	3	4 .	. 5	6	
Have you caten in secret? (Do not count binges.)	0	1	2	3	4	5	6	
D. Have you definitely wanted your stomach to be flat?	0	1	2	3	4	5	6	
1. Has thinking about your shape or weight made it more difficult to concentrate on things you are interested in; for example read, watch TV, or follow a conversation?	0	1	2	3	4	5	6	
2. Have you had a definite fear that you might gain								
weight or become fat?	0	11	2	3	44	5	6	
3. Have you felt fat?	0	1	2	3	4	5	6	
4. Have you had a strong desire to lose weight?	0	1	2	3	4	5	6	

15. OVER THE PAST FEW WEEKS (28 DAYS)		
On what proportion of times that you have eaten have you	0 - None of the times 1 - A few of the times	4 - More than half the times 5 - Most of the time
felt guilty because of the effect on your shape or weight?	2 - Less than half the times3 - Half the times	6 - Every time
(Do not count binges) Circle the number that applies.		

16.	6. Over the past four weeks (28 days), have there been any times when you have felt that you have							
	eaten what other people would regard as an unusually large amount of food given the							
	circumstances? (Please put appropriate number in blank.)							
17.	How many such episodes have you had over the past four weeks?							
18.	During how many of these episodes of overeating did you have a sense of having lost co	ontrol ov	er your eating?	,				
19.	Have you has other episodes of eating in which you have had a sense of having lost con	trol and					0 - No	
	eaten too much, but have not eaten an unusually large amount of food given the circums	stances?					1- Yes	
20.	How many such episodes have you had over the past four weeks?							
21.	Over the past four weeks have you made yourself sick (vomit) as a means of controlling	g your					0 - No	
	shape or weight?						1 - Yes	
22.	How many times have you done this over the past four weeks?							
23.	Have you taken laxatives as a means of controlling your shape or weight?						0 - No	
							1 - Yes	
24.	How many times have you done this over the past four weeks?							
25.							0 - No	· · · · · · · · · · · · · · · · · · ·
-0.	25. Have you taken diuretics (water tablets) as a means of controlling your shape or weight?							
							1 - Yes	
26.	How many times have you done this over the past four weeks?							
27.	27. Have you exercised hard as a means of controlling your shape or weight?							
							1 - Yes	
28.	How many times have you done this over the past four weeks?							
					_			
			Not at all	Slightly	A	Ioderately	Markedly	
	OVER THE PAST FOUR WEEKS (28 DAYS) Please circle the number which best describes your behavior.	0	1	2	3	4	5	6
29.	Has your weight influenced how you think about (judge) yourself as a person?	0	1	2	3	4	5	6
30.	Has your shape influenced how you think about (judge) yourself as a person?	0	1	2	3	4	5	6
31.	How much would it upset you if you had to weigh yourself once a week for the next 4 weeks?	0	1	2	3	4	5	6
32.	How dissatisfied have you felt about your weight?	0	1	2	3	4	5	6
33.	How dissatisfied have you felt about your shape?	0	1	2	3	4	5	6
34.	How concerned have you been about other people seeing you eat?	0	İ	2	3	4	5	6
35.	How uncomfortable have you felt seeing your body; for example, in the mirror, in shop window reflections, while undressing or taking a bath or shower?	0	1	2	3	4	5	6
36.								-
	How uncomfortable have you felt about others seeing your body; for example, in communal changing rooms, when swimming or wearing tight clothes?	0	1	2	3	4	5	6

Ideal-body Stereotype Scale-Revised

We want to know what you think attractive women look like. How much do you agree with these statements?	Strongly disagree 1	Somewhat disagree 2	Neither agree nor disagree 3	Somewhat agree 4	Strongly agree 5
1. Thin women are more attractive.	1	2	3	4	5
2. Tall women are more attractive.	11	2	3	44	5
Women with toned bodies are more attractive.	1	2	3	4	5
4. Slim women are more attractive.	1	2	3	4	5
Women who are in shape are more attractive.	1	2	3	4	5
6. Slender women are more attractive.	11	2	3	4	5
Women with long legs are more attractive.	1	2	3	4	5
8. Curvy women are more attractive.	11	2	3	4	5
9. Shapely women are more attractive.	1	2	3	4	5
10. Women who are taller are more attractive.	11	2	3	4	5

Health Care Utilization

How often did you speak to the following providers about these topics over the last MONTH?

<u>TOPIC</u>	A primary care doctor or other physician:	A psychiatrist:	A nurse:	A therapist, psychologist, or other counselor:	A support group (excluding a group related to this study):
Physical health problem, injury, or illness	hours	hours	hours	hours	hours
2) Mental health problem (depression, anxiety, etc.)	hours	hours	hours	hours	hours
3) Weight problem:	hours	hours	hours	hours	hours
4) Eating disorder or body image concern:	hours	hours	hours	hours	hours
5) Other personal problem:	hours	hours	hours	hours	hours
How often did you speak to the	he following pr	oviders about t	hese topics ove	er the last YEAI	₹?
TOPIC	A primary care doctor or other physician:	A psychiatrist:	A nurse:	A therapist, psychologist, or other counselor:	A support group (excluding a group related to this study):
Physical health problem, injury, or illness	hours	hours	hours	hours	hours
2) Mental health problem (depression, anxiety, etc.)	hours	hours	hours	hours	hours
3) Weight problem:	hours	hours	hours	hours	hours
4) Eating disorder or body image concern:	hours	hours	hours	hours	hours
5) Other personal problem:	hours	hours	hours	hours	hours

TEAMMATE RELATIONSHIP HEALTH

Please circle the response that reflects how your relate to your teammates.

Never	Almos Never	t So	metime Ofte		rly V ften	/ery
 Even when I have difficult things to share, I can be honest and real with my teammates. 	1	2	3	4	5	
2. After a conversation with my teammaets, I feel uplifted.	1	2	3	4	5	
3. The more time I spend with my teammates, the closer I feel to them.	1	2	3	4	5	
 My friendship with my teammates inspires me to work to strengthen these friendships. 	1	2	3	4	5	
I have a greater sense of self-worth though my relationships with my teammates	1	2	3	4	5	
6. I can tell my teammates when they have hurt my feelings	1	2	3	4	5	
7. My friendship with my teammates causes me to grow in important ways	1	2	3	4	5	
8. After spending time together, I feel energized.	1	2	3	4	5	

Knowledge about the Female Athlete Triad

- 1. What are the three components to the Female Athlete Triad?
 - a. Serious eating disorder, never having started menstruating (i.e., period), problems with bone density
 - b. Inadequate energy intake, cardiac problems, problems with bone density
 - c. Inadequate energy intake, irregular or no menstruation (i.e., periods), problems with bone density
 - d. Irregular or no menstruation, eating disorders, cardiac problems
- 2. True or False: You must have all three components of the Female Athlete Triad before your health is at any risk.
- 3. **True** or False: The female athlete triad may include a fourth component in the future and that component would be cardiac problems.
- 4. True or False: If you consume enough calcium it doesn't matter if you stop menstruating (i.e., having your periods). Your bones will be fine.
- 5. True or False: You can easily build bone throughout your lifespan (i.e., as long as you live).
- 6. **True** or False: Many female athletes mistakenly do not consume enough calories/nutrients for their active lifestyles and end up having the Female Athlete Triad without intending to do so.
- 7. **True** or False: The birth control pill may restart menstruation in someone with the Female Athlete Triad, but it won't fix the problems with bone density.
- 8. **True** or False: If you take birth control pills, you may have the Female Athlete Triad and not know it because the pill can mask the most obvious symptom (loss of menstruation).
- 9. True of False: If you have the Female Athlete Triad it means you have an eating disorder.
- 10. True or **False**: Most athletes with eating disorders don't have to worry about getting the Female Athlete Triad because it is rare.

PANAS-X

We would like to know how you have been feeling over the past few weeks. Please mark the appropriate number, which best reflects your agreement with each statement.

1 Very Slightly or Not at all	2 A little		3 Moderately	4 Quite a Bit	5 Extremely
Nervous					
Disgusted with self					
Guilty		<u> </u>		4	
Angry with self					
Afraid					
Dissatisfied with se	elf				
Alone				•	•
Blameworthy					
Frightened					
Sad					
Jittery					
Blue					
Downhearted					
Scared		···			
Lonely					
Shaky					
Ashamed					

INTERVENTION SUITABILITY/EXPECTATIONS

1. At this i 1 not at all l	•	2	3	4		6	fered to 7	you see 8 very lo	9	
2. At this 1 not at all l	•	2	3	4	5	6	7	8	neficial t 9	o you?
3. How co is a femal 1 not at all	le ath	nlete? 2	id you k 3	4	commer 5 vhat cor	6	7	8	to a frie 9 onfident	
occur?			ntervent 30%			improv	ement i 70%	n your r 80%	elations	ship with your body do you think will
5. At this your body		, how n	nuch do	you re	ally feel	that thi	s interv	ention v	vill help	you to have a better relationship with
1 not at all		2	3	4 some	5 what	6	7	8	9 Very m	nuch

Study Information Questionnaire

- 1. What does UFO stand for?
 - a. unidentified flying object
 - b. unidentifiable food-like object
 - c. unattractive foot odor
 - d. unfamiliar food objects
 - e. unidentified fagioli all'olio
- 2. Athlete fat talk in the locker room is not a problem and helps teammates bond (T/F)
 - a. True
 - b. False
- 3. What is a mirror exercise?
 - a. Working out in front of a mirror
 - b. Looking into your mirror after workouts
 - c. Mirroring someone like a mime
 - d. Using a mirror to perfect your form on an exercise
 - e. Writing down your positive qualities in front of a mirror
- 4. What is the list of The World's Healthiest Foods?
 - Website of foods that your mom thinks is good for you.
 - b. A website of nutrient dense foods.
 - c. Website of foods that taste really bad.
 - d. A website of foods like energy bars and protein shakes
 - e. A website of foods of low fat and low carb foods.
- 5. What is the Energy Balance Equation?
 - a. An energy equation that Einstein invented to create the speed of light.
 - b. An energy equation that explains body weight is the result of calorie intake and output.
 - c. An energy equation that Thomas Edison invented to create the light bulb.
 - d. An energy equation used in balancing your hormones to promote weight maintenance.
 - e. An energy equation that explains how to lose weight without trying
- 6. Crumbly bones is another term for
 - a. Osteoblast
 - b. Low bone density
 - c. Ground up bones used to fertilize plants
 - d. Bones of very young children
 - e. Bones of very old women
- 7. The athlete-specific healthy-ideal

- a. Is super lean with defined muscles
- b. Is defined by how much weight a person can lift
- c. Has no specific look and varies athlete to athlete
- d. Looks good in any type of athletic uniform
- e. Is useful for being healthy, but not athletic performance
- 8. What are benefits of attaining the athlete-specific healthy- ideal?
 - a. Higher quality of life
 - b. Lower rates of depression
 - c. Feeling stronger
 - d. feel energized in class so you can make grades to maintain GPA requirement
 - e. All of the Above
- 9. What is the key triggering factor in menstrual disorders in female athletes?
 - a. The athletes do not get enough sleep during the weeks leading up to their period.
 - b. The athletes can't remember and keep track of their menstrual schedule.
 - c. The athletes don't get enough calories or nutrients.
 - d. The athletes have weak bones and need to drink more milk.
 - e. None of the above
- 10. It is possible to prevent the onset of the Female Athlete Triad. (T/F)
- a. True
- b. False

Self- Perception of Performance Questionnaire

- 1. Please rate the usefulness of the following strategies to improve my sport performance:
- 1= Not useful at all
- 2= Moderately not useful
- 3=Somewhat not useful
- 4=neutral- neither not useful or useful
- 5= Somewhat useful
- 6= Moderately useful
- 7=Extremely useful
- a. Get adequate sleep
- b. Eat nutrient dense foods
- c. Lose weight
- d. Lose body fat
- e. Adhere to my coaches' instructions for training
- f. Focus on making my abs look very defined
- g. Adhere to my coaches' instructions for rest
- h. Limit my alcohol consumption
- i. Make sure I consume enough energy (calories)
- j. Try to achieve the "look" (body type) often stereotypically associated with my sport
- k. Avoid smoking
- I. Limit consumption of empty calories (or ufos)
- m. Look good in my uniform
- n. balance my eating with my training load.
- o. increase caloric intake when increasing training load.
- p. eat well to perform well.
- g. none of the above
- 2. The last five times I participated in my official sports events, e.g. meets, games, etc. , I would rate my performance :

1= worst I've ever performed,

2=moderately poor performance

3=somewhat poor performance

4 (neutral) neither poor nor good performance

5=somewhat good performance

6=moderately good performance

7=best I've ever performed

3. The last five times I participated in my official sports events, e.g. meets, games, etc. , I would rate my stamina/endurance/energy:

1= lowest stamina ever

2=moderately low stamina

3=somewhat low stamina

4= (neutral) neither low or high stamina 5=somewhat high stamina 6=moderately high stamina 7=highest/best stamina ever

4. The last five times I participated in my official sports events, e.g. meets, games, etc. , I would rate my strength:

1= lowest strength ever
2=moderately low strength
3=somewhat low strength
4= (neutral) neither low or high strength
5=somewhat high strength
6=moderately high strength
7=highest strength ever

Athlete Body Project Eating Questionnaire

Read the questions below and circle the answer that best describe your eating habits.

- 1. Over the past week, how often did you consume simple, whole foods with easy to pronounce ingredients because they are markers of unprocessed foods?
 - a. I choose these foods every day.
 - b. At least twice a day
 - c. About 3 times a week
 - d. Less than twice a week
 - e. I never eat these types of foods.
- 2. To what extent does a food product's ingredient list and nutrition label drive your decision to consume or avoid that food product?
 - a. The ingredient list/nutrition label plays a definite role in my food choices.
 - b. Over half of my food choices are driven by the ingredient list/nutrition label.
 - c. About half of my food choices are driven by the ingredient list/nutrition label.
 - d. Less than half of my food choices are driven by the ingredient list/nutrition label.
 - e. The ingredient list/nutrition label does NOT drive my food choices.
 - f. I never read the ingredient list/nutrition label.
- 3. Over the past week, how often did you consciously try to increase the nutrient density of your meal (choose nutrient rich foods instead of foods with empty calories)?
 - a. I consume nutrient rich alternatives on a daily basis
 - b. At least twice a day
 - c. About 3 times a week
 - d. Less than twice a week
 - e. I never eat nutrient rich alternatives
- 4. Over the past week, how often did you eat fresh fruits and vegetables?
 - a. I eat fresh fruits and/or vegetables with every meal.
 - b. At least twice a day
 - c. About 3 times a week
 - d. Less than twice a week
 - e. I never eat fresh fruits and/or vegetables.

Never

5.	When traveling, how likely are you to plan ahead for healthy meals and snacks to keep your meal plan
	consistent with your normal daily routine?

- a. I pack all of my healthy snacks ahead of time, and always plan ahead for healthy restaurant meals.
- b. At least half of my meals and snacks are pre-planned.
- c. I plan my meals and snacks ahead of time, but do not stick to my plan once I am on the road.
- d. I do not plan ahead for meals and snacks, and am often forced to consume empty-calorie, processed when on the road.

	processed w	hen on the r	oad.				
	Read the questions tatement is TRUE					often the	
6.	The majority of my only estudents who only estry to pick foods that	at on campu	is, and do not gro	cery shop reg	<i>ularly</i> : Even wh		
	Never						
			Always				
7.	I avoid foods with highly processed to	-	se corn syrup ar 3	nd hydrogena 4	ted oils becau 5	se they are ma 6	rkers of
	Never						
			Always				
8.	I incorporate fiber ri plan.	ch foods suc	ch as oatmeal, wh	nole grains, leg	umes, and bea	ns into my daily	meal
	1	2	3	4	5	6	

Always

9.	avocados, and ol	my fat intake is t live oil.	rom foods that	provide good	ials such as naz	kseed, walliuts				
	1	2	3	4	5	6				
	Never									
	Always									
10. I drink water instead of caffeinated or carbonated sweet beverages to stay hydrated.										
	1	2	3	4	5	6				
	Never									
Always										

1. I enjoyed participating in the program

2. I feel I benefited from participating in this program:

a. Yes b. No

a. Yes- why?b. No- why?

Program Satisfaction Questionnaire

	3. As a result of completing this program, I feel that I obtained information that could improve my sport performance							
	a. Yes- what?							
	b. No- why?							
,	4. This program helped me understand the important role played by good nutrition in sport performance.							
	a. Yes- how?							
	b. No-How?							
	D. 140-11044:							
	5. This program helped me understand why it is better to strive for the athlete-specific healthy ideal instead of the sport specific thin-ideal. a. Yes- how?							
	b. No- how?							
	6. This program helped me understand the important role played by balance in training and rest i	n						
	sport performance.							
	a. Yes- how?							
	b. No- how?							

Contextual Body Image Questionnaire-Athlete (CBIQA)

What is your academic classification?			What is the highest level of athletic-related financial aid that you re-				
	Freshman			A full athletic scholarship			
	Sophomore			A partial athletic scholarship			
	Junior			Other financial aid related to athletic ability			
	Senior			No athletic scholarship			
	Graduate Student			Not applicable			
	Other (please specify):						
	•	,		·			
Ho	w many years have you be 3 years, fill in 0 in the first	been training for this spo	ort? Please f	ill out both columns. For example, if you've trained in your Sport			
jor	(S) years, jui in 0 in ine just	©	a commi				
	①	1					
	2	2					
	3	3					
	4	4					
	(5)	(5)					
	6	6					
	7	⑦					
	8	8					
	9	9					

Instructions: These questions deal with how satisfied you are with your body and your appearance. You will be asked questions regarding aspects of your body image IN YOUR DAILY LIFE (OUTSIDE OF SPORT). There are no right or wrong answers. Do not think too long about your answers and do not skip any questions.

IN YOUR DAILY LIFE, please rate the following items regarding your appearance from "Very Ugly" to "Very Beautiful" by selecting the choice that best describes your response.

		<u>Very</u> <u>Ugly</u>	<u>Ugly</u>	Somewhat Ugly	Neither Ugly, Nor Beautiful	Somewhat Beautiful	<u>Beautiful</u>	<u>Very</u> <u>Beautiful</u>	
[think my appearance is:									
[think my appearance compared to oth	ers is:								
Others think my appearance is:									
IN YOUR DAILY LIFE, please rate the following items regarding your body shape from "Much Too Thin" to "Much Too Fat" by selecting the choice that best describes your response.									
	_	Much oo thin	<u>Too</u> thin	Somewhat too thin	Neither too thin, nor too fat	Somewhat too fat	<u>Too fat</u>	Much too	
[think my body shape is:	,								
I think my body shape compared to oth	ers is:								
Others think my body shape is:									
IN YOUR DAILY LIFE, please rate Musc				g your muscula that best descr			nuscular" to	"Much Too	
	Much too unmuscula	_	Too nmuscular	Somewhat too unmuscular	Neither too little, nor too muscular	Somewhat too muscular	Too muscular	Much too muscular	
I think the muscularity of my body s:									
I think the muscularity of my body compared to others is:									
Others think the muscularity of my body is:		·							

IN YOUR DAILY LIFE, please rate the following items regarding your weight/body composition from "Much Too Low" to "Much Too High" by selecting the choice that best describes your response.

	Much too low	Too low	Somewhat too low	Neither too low, nor too high	Somewhat too high	<u>Too high</u>	Much too high		
think my body weight is:									
think my fat percentage is:									
think my body weight compared to others s:									
think my fat percentage compared to others is:									
Others think my body weight is:									
Others think my fat percentage is:									
Instructions: These questions deal with horegarding aspects of your body image IN Young about your answers and do not skip a	OUR SPOR	T ENVIRO	your body an	nd your appear ere are no right	ance. You will for wrong ans	l be asked qu swers. Do no	estions t think too		
IN YOUR SPORT ENVIRONMENT, Beautiful				ing your appea ribes your resp		ery Ugly" to	o "Very		
	<u>Very</u> <u>Ugly</u>	<u>Ugly</u>	Somewhat Ugly	<u>Neither</u> <u>Ugly, Nor</u> <u>Beautiful</u>	Somewhat Beautiful	<u>Beautiful</u>	<u>Very</u> <u>Beautiful</u>		
I think my appearance is:									
I think my appearance compared to others s:									
Others think my appearance is:									
YOUR SPORT ENVIRONMENT, please rate the following items regarding your body shape from "Much Too Thin" to "Much Too Fat" by selecting the choice that best describes your response.									

	<u>Much to</u> <u>thin</u>	00 Too thin	Somewha t too thin	Neither too thin, nor too fat	Somewhat too fat	Too fat	Much too fat
I think my body shape is:							
[think my body shape compared to othe s:	rs						
Others think my body shape is:							
IN YOUR SPORT ENVIRONMENT, "Much Too	please rate the Muscular" by					uch Too Unn	nuscular" to
	Much too nmuscular	<u>Too</u> unmuscular	Somewhat too unmuscular	Neither too little, nor too muscular	Somewhat too muscular	<u>Too</u> muscular	Much too muscular
I think the muscularity of my body s:	. 🗆		. 🗆		, 0		. 🗆
I think the muscularity of my body compared to others is:							
Others think the muscularity of my ody is:							
IN YOUR SPORT ENVIRONMENT Low" to "Muc	Γ, please rate t h Too High" b	the following i	tems regardin e choice that b	g your weigh est describes	it/body compos	sition from "	Much Too
	Much too low	O Too low	Somewha t too low	Neither too low, nor too high	Somewhat too high	Too high	Much too high
I think my body weight is:							
I think my fat percentage is:							
I think my body weight compared to oth s:	ers \Box						
I think my fat percentage compared to others is:							
Others think my body weight is:							
Others think my fat percentage is:							

Currently In Sport

STOP!

Are you currently in your sport?

Yes-Please complete the rest of the questionnaires.
No- STOP. Do not complete the rest of the questionnaires.

Training Attitudes Scale

	Never	Rarely	Sometimes	<u>Often</u>	Always
I train more than is required by my coach.					
I train/exercise against the advice of the medical/training staff.					
I weigh myself after training/exercise.					
I train despite being injured.					
I feel guilty when I don't train/exercise.					
I feel anxious when I don't train/exercise.					
I feel that I need to train more than my teammates.					
I worry about my weight when I can't/don't train/exercise.				O	
It is hard for me to change/alter my training routine/schedule.					
It is difficult for me to take a day off from training.					
I think that I am not training hard enough.					
I get "overuse" injuries.					
I exercise longer than I had planned.					0
I exercise when I feel depressed.					
I exercise outside of team practices.					
I exercise no matter what.					
I feel stressed or tense before I exercise.					

These items ask about your attitudes, feelings, and behaviors regarding exercise and training. For each item, select whether you STRONGLY AGREE, AGREE, NEITHER AGREE NOR DISAGREE, DISAGREE, or STRONGLY DISAGREE. Remember, there are no right or wrong answers. Please answer all items.

	Strongly Agree	Agree	Neither agree nor disagree	<u>Disagree</u>	Strongly Disagree
No matter how hard I train, I am not satisfied with my conditioning.					
No matter how hard I train, I am still not lean enough.					
No matter how hard I train, I am still not thin enough.					
I prefer to train alone.					
The right amount of exercise has to involve pain.					
Unless I am exhausted after a workout, I don't feel that I have trained hard enough.					
My primary reason for training hard is to please my coach.					
I train hard so my teammates will not be disappointed in me.					
The worst part of being injured is that I can't train.					
The worst part of being injured is that I will gain weight.		0			0
The worst part of being injured is that I will decondition.					
An athlete can train too much.					
I prefer to train the same way (same exercises, same schedule, etc.) every day.					
No matter how hard I train, I am not pleased with my body.					
The more I exercise, the better I feel.					
I do not feel good if I miss a day of training/exercise.					
I exercise outside of practice to lose weight.					
I exercise outside of practice to build bigger muscles.					

Female Athlete triad Identification (for trainers/ coaches/ staff)

How many student athletes have presented to your staff out of concern they may have one or more components of the Female Athlete Triad (i.e., the student explicitly stated that she is concerned about the Triad).